PREMARKET NOTIFICATION [510(K)] SUMMARY

APR 2 7 2001

K000889

Applicant name:

Senoj™ Biocare, Inc.
2021 Santa Monica Blvd., Suite 408-E
Santa Monica, CA 90404
(310) 829-5430
(310) 829-5587 (fax)

Contact Person: Dr. Shedrick D. Jones, President
Date Summary Prepared: December 4, 1999

Device Name:
Trade Name: Senoj Implant System
Common Name: Dental Implant
Classification Name: Endosseous Implant

Claiming Substantial Equivalence To:
Icon Implant System -- Bio Science Technologies, Inc.
Phoenix Opti-Max Dental Implant -- Phoenix Dental, Inc.

Device Description
The Senoj™ Implant is available as an extended neck implant or a standard neck implant. Each are a one-stage, self-tapping implant, incorporating:

1. A threaded titanium cylindrical implant with helical channels and through-holes,
2. The threaded implants are approximately 3.75 mm in diameter, and are provided in 8, 10, 13 and 15 mm lengths.
3. Implants are offered coated with hydroxylapatite or plasma sprayed titanium.

The Product and Its Intended Use
Senoj™ Biocare, Inc.'s Senoj Implant System consists of a screw implant and a cover screw, which are contained within a titanium (CP) canister. An actual implant is provided for the Reviewer. The implant and cover screw are nearly identical to the Icon Implant and the Phoenix Opti-Max Dental Implant.

The Senoj™ Implant System is intended for use in the following:

Uses for the extended neck implant:

1. Single tooth replacement in either the maxilla or mandible by means of a full crown.

Uses for the standard neck implant (also for the extended neck implant, but with no abutment necessary):

2. Terminal or intermediary abutment for fixed bridgework in maxilla or mandible. These abutments can be bridged to natural teeth or another implant abutment.
3. Overdenture retention for the totally or partially edentulous mandible or maxilla using an overdenture bar, o-ring attachment, dalla bona, or hader bar. Two or more abutments are required.
4. Multiple abutments (2-6) connected by a cast bar, designed to interface with an overdenture in the fully or partially edentulous maxilla or mandible. The overdenture is patient-removable for hygiene purposes.
5. Multiple abutment use (3-6) connected by a cast base upon which denture is fabricated (artificial teeth and gingiva), which is screws-retained to the abutments, and is not patient-removable.
6. Single or multiple abutments for use as orthodontic anchorage.

Summary of Technological Characteristics
When compared to the predicate devices, the Senoj ™ Implant System is not technically different. Differences between the products are design differences.

Performance Data: N/A

Nonclinical Data: N/A

Clinical Data: N/A

-- END OF 510 (k) SUMMARY --

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

Senoj Biocare, Incoporated
C/O Ms. Penny Wollum
Regulatory Affairs Manager
Pacific Regulatory Services, Incorporated
8910 University Center Lane
San Diego, California 92122-1085

Re: K000889
Trade Name: Senjo Implant System
Regulatory Class: III
Product Code: DZE
Dated: March 14, 2001
Received: March 19, 2001

Dear Ms. Wollum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000889

Device Name: Senoj Implant System

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000889

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)